Veterinary Medicines Directorate

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Post Authorisation Assessments

Rompun 2% w/v Solution for Injection

Vm 52127/5078

07 July 2025	Change in the address of a manufacturer of the finished product.
29 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
28 March 2025	Change of Marketing Authorisation Holder from: Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to: Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, D-27472 Cuxhaven, Germany.
05 March 2025	Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product.
18 February 2022	Change in the name of the manufacturer of the finished product.
13 October 2020	Change in the name and address of the manufacturer of the finished product.
17 September 2020	Change of MAH from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
18 September 2018	Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green park, Reading, Berkshire, RG2 6AD.
21 February 2018	Deletion of manufacturing site for an active substance.
05 May 2017	Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD.
27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
18 November 2015	Update of a manufacturing site address for secondary assembly only.
14 September 2015	Submission of a new certificate of suitability.
03 December 2012	Change of name of manufacturer of stoppers.
11 June 2012	Change of name of manufacturer of the active substance.
20 July 2012	Update to the Part II dossier.
22 February 2011	Change of distributor.
17 November 2009	Addition of precautionary statements to section 4.5ii of the SPC and package leaflet.
19 February 2009	Change in the name and/or address of a manufacturer of the active substance.
28 January 2009	Decrease in cattle milk and meat withdrawal periods.
22 May 2008	Changes to the SPC regarding horse withdrawal period.
24 January 2007	Increase in shelf life of the finished product.

28 June 2006	Changes to the SPC and product literature to bring them into line with new legislation.
15 May 2006	Change in sterilisation method.
15 May 2006	Change in formulation of the finished product.
15 May 2006	Change to finished product packaging.
16 February 2006	Renewal.
07 January 2005	Change of the name/address of the active substance manufacturer.
23 December 2004	Change to address of the manufacturer of dosage form.
24 September 2004	Change of withdrawal period in horse meat in accordance with Horse Passport legislation.
06 February 2004	Change to cattle meat withdrawal period.
08 October 2003	Change of address of MAH.
02 May 2003	Addition of a manufacture of dosage form.
30 April 2003	Introduction of a withdrawal period for cattle.
13 August 2001	Renewal.
27 April 2000	Change to milk withdrawal period.
26 April 1996	Change of MAH.